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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/822,533 | 04/12/2004 | Daniel J. O'Sullivan | 110.01290102 | 3326 |

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,533

Applicant(s)

O'SULLIVAN, DANIEL J.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/28/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to isolated *Bifidobacterium* strains, classified in class 435, subclass 252.1.
- II. Claims 9-15, 27, and 38-39, drawn to methods for inhibiting and/or preventing replication of microbes in various sites related to food or digestion thereof, classified in class 426, subclass 321.
- III. Claims 16-19, drawn to a method for treating lactase deficiency, classified in class 435, subclass 7.9.
- IV. Claims 20-26, drawn to method for establishing a *Bifidobacterium* flora, classified in class 424, subclass 551.
- V. Claim 28, drawn to method for decreasing the risk of colon cancer, classified in class 435, subclass 29.
- VI. Claim 29, drawn to a composition for inhibiting replication of a microbe, classified in class 424, subclass 93.4.
- VII. Claims 30-32, drawn to methods for obtaining and preparing a siderophore, classified in class 435, subclass 243.
- VIII. Claims 33-35, drawn to a composition comprising a siderophore and isolated siderophores, classified in class 435, subclass 242.

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- IX. Claims 36-37, drawn to methods for decreasing the amount of free iron in a composition, classified in class 502, subclass 406.
- X. Claims 40, drawn to a method for altering the expression of a siderophore, classified in class 435, subclass 41.
- XI. Claims 41-47, drawn to a composition comprising an isolated *Bifidobacterium* in a beverage, classified in class 99, subclass 275.
- XII. Claims 48-58, drawn to a method for administering a live microbial feed, classified in class 426, subclass 53.

The inventions are distinct, each from the other because of the following reasons:

Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as by culturing a *Bifidobacterium* in a medium containing iron and producing a siderophore in the medium, binding the siderophore to the iron, and then extracting iron from the medium to obtain the siderophore without the need for sterilization.

Each of the products of groups I, VI and XI are different and distinct from each other because in Group I an isolated specific strain is not required to be in a beverage and the isolated *Bifidobacterium* of XI is not the same strain as required of Group I. Therefore, the search for Group I is different from the search for Group VI, and XI.

Further, Group VI is required to be capable of providing a siderophore of which this feature is not required of Groups I and XI. Therefore, there exists a two way distinctness between each of the product claims of Groups I, VI and XI. Methods as set forth in each of Groups II, III, IV, V, X, IX and XII each require different process steps for carrying out the respective methods. Therefore, there is two way distinctness between each of these method groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

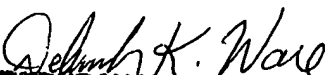
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
January 19, 2006